UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

November 20, 1998

MEMORANDUM

EPA File Symbol: 71788-R DRI-OUT™
DP Barcode: D248699
Case No: 062540

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505C)

Byron T. Backus 11/20/98
Hashmi 11/20/98

To: John Leahy/Susan Lewis, PM 03
Insecticide Branch
Registration Division (7505C)

Registrant: Home Saving Termite Control, Inc.

ACTION REQUESTED: "Please review acute tox data for new product registration: MRIDs 446137-04, -05, -06, -07, -08, & -09."

COMMENTS AND RECOMMENDATIONS: The six studies have all been classified as acceptable, and the product, EPA File Symbol: 71788-R DRI-OUT™ has the following acute toxicity profile:

Acute Oral LD50	IV	Acceptable
Acute Dermal LD50	IV	Acceptable
Acute Inhalation LC50	IV	Acceptable
Primary Eye Irritation	III	Acceptable
Primary Dermal Irritation	IV	Acceptable
Dermal Sensitization	No	Acceptable

It is noted that the proposed label has (under **ENVIRONMENTAL HAZARDS**) the statements "Not known to have any adverse effect on the aquatic environment. Insoluble and non-toxic." This could be construed as a safety claim for this pesticide, and is not acceptable.

The following is the precautionary labeling for this product, based on the acute toxicity profile given above, and as obtained from the Label Review System:

Date: 11/20/98 LABEL REVIEW SYSTEM

ID #: 071788-00001 Dri-Out

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS:

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

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DATA EVALUATION REPORT

DRI-OUT™

STUDY TYPES: ACUTE ORAL TOXICITY - RAT (81-1)
ACUTE DERMAL TOXICITY - RAT (81-2)
ACUTE INHALATION TOXICITY - RAT (81-3)
PRIMARY EYE IRRITATION - RABBIT (81-4)
PRIMARY DERMAL IRRITATION - RABBIT (81-5)
DERMAL SENSITIZATION - GUINEA PIG (81-6)

SUMMARY: ACUTE TOXICITY ONE-LINERS (81-1 through 81-6)

Prepared for

Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831

Primary Reviewer:
Susan Chang, M.S.
Signature: Robert H. Ross for S.S. Chang
Date: NOV 09 1998

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.),Ph.D., D.A.B.T.
Signature: H T Borges
Date: NOV 09

Robert H. Ross, M.S., Group Leader
Signature: Robert H. Ross
Date: NOV 09

Quality Assurance:
LeeAnn Wilson, M.A.
Signature: L. A. Wilson
Date: NOV 09 1998

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (870.1100, formerly §81-1)

Product Manager: 03
MRID No.: 44613704

Contract Reviewer: Susan Chang
EPA Reviewer: Byron T. Backus, Ph.D.
Study Completion Date: June 24, 1998
Study No.: 5870

Testing Facility: Product Safety Labs
Author: Wnorowski, G.

Quality Assurance (40 CFR §160.12): Included (p. 15)

Test Material: DRI-OUT™ (>99.7% Amorphous silica gel); Lot 7011; fine white powder
Species: Rats; Albino, Sprague-Dawley derived
Age: Young adult
Weight (fasted): Males: 203-218 g; Females: 165-185 g
Source: Ace Animals, Inc., Boyertown, PA

Conclusion:

1. **LD_{50} (mg/kg):**
   Males: > 5000 mg/kg
   Females: > 5000 mg/kg
   Combined: > 5000 mg/kg
2. **The estimated LD_{50} is** > 5000 mg/kg
3. **Tox. Category:** IV **Classification:** Acceptable

Procedure (including deviations from 870.1100): The test material was administered as a 15% w/w suspension in distilled water.

Results:

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Combined
5000	0/5	0/5	0/10

Observations: No rats died during the study. All rats appeared active and healthy with normal body weight gains.

Gross Necropsy: Gross necropsy findings were generally unremarkable. All rats had moderately red lungs due to CO_2 inhalation euthanasia.

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DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (870.1200, formerly §81-2)

Product Manager: 03
MRID No.: 44613705

Contract Reviewer: Susan Chang
EPA Reviewer: Byron T. Backus, Ph.D.
Study Completion Date: June 24, 1998
Study No.: 5871

Testing Facility: Product Safety Labs
Author: Wnorowski, G.

Quality Assurance (40 CFR §160.12): Included (p. 15)

Test Material: DRI-OUT™ (>99.7% Amorphous silica gel); Lot 7011; fine white powder
Species: Rats; Albino, Sprague-Dawley derived
Age: Young adult
Weight: Males: 226-249 g; Females: 205-217 g
Source: Ace Animals, Inc., Boyertown, PA

Dermal LD_{50} Testing:

Conclusion:

1. **LD_{50} (mg/kg):**
   Males: > 5000 mg/kg
   Females: > 5000 mg/kg
   Combined: > 5000 mg/kg
2. **The estimated LD_{50} is** > 5000 mg/kg
3. **Tox. Category:** IV **Classification:** Acceptable

Procedure (including deviations from 870.1200): The test material was "moistened to a dry paste with distilled water and applied to the skin of ten healthy rats for 24 hours."

Results:

Dosage (mg/kg)[a]	Number of Deaths/Number Tested		
	Males	Females	Combined
5000 [b]	0/5	0/5	0/10

[a] The test material was moistened with distilled water to achieve a dry paste by preparing a 25% w/w mixture.
[b] Dry weight basis

Observations: No rats died during the study. All rats appeared active and healthy with normal body weight gains.

Gross Necropsy: Gross necropsy findings were generally unremarkable. All rats had slightly or moderately red lungs due to CO_2 inhalation euthanasia.

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DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (870.1300, formerly §81-3)

Product Manager: 03
MRID No.: 44613706

Contract Reviewer: Susan Chang
EPA Reviewer: Byron T. Backus
Study Completion Date: June 24, 1998
Study No.: 5872

Testing Facility: Product Safety Labs
Author: Wnorowski, G.

Quality Assurance (40 CFR §160.12): Included (p. 23)

Test Material: DRI-OUT™ (>99.7% Amorphous silica gel); Lot 7011; fine white powder
Species: Rats; Albino, Sprague-Dawley derived
Age: Young adult
Weight: Males: 210-239 g; Females: 205-226 g
Source: Ace Animals, Inc., Boyertown, PA

Conclusion:

1. **LC_{50} (mg/L):**
   Males: > 2.22 mg/L
   Females: > 2.22 mg/L
   Combined: > 2.22 mg/L
2. **The estimated LC_{50} is** >2.22 mg/L
3. **Tox. Category:** IV **Classification**: Acceptable

Procedure (including deviations from 8700.13): "Prior to aerosolization, the test substance was ground in a ball mill for 24 hours."

Exposure Concentration mg/L ± S.D. (Gravimetrically Determined)	Number of Deaths/Number Tested		
	Males	Females	Combined
2.22 ± 0.31	0/5	0/5	0/10

Clinical Observations: The test material was on the fur of all rats. The rats exhibited hunched posture and hypoactivity during exposure. Ocular and/or nasal discharge were observed in all rats at chamber removal. All rats recovered within 19 hours and had normal body weight gains.

Gross Necropsy Findings: Gross necropsy findings were generally unremarkable. All rats had moderately red lungs due to CO_2 inhalation euthanasia.

Chamber Atmosphere		
Grav. Conc.	MMAD	GSD
2.22 mg/L	1.7-1.8 µm	3.16-3.22

Other Information: Approximately 70% of particles had an aerodynamic diameter ≤3.3 µm. The nominal concentration was 28.55 mg/L.

Chamber Environment [a]	
Chamber Volume	100 L
Airflow	50.8 LPM
Temperature	70-72°F
Relative Humidity	50-55%

[a] Whole body

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DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (870.2400, formerly §81-4)

Product Manager: 03
MRID No.: 44613707

Contract Reviewer: Susan Chang
EPA Reviewer: Byron T. Backus, Ph.D.
Study Completion Date: June 24, 1998
Study No.: 5873

Testing Facility: Product Safety Labs
Author: Wnorowski, G.

Quality Assurance (40 CFR §160.12): Included (p. 21)

Test Material: DRI-OUT™ (>99.7% Amorphous silica gel); Lot 7011; fine white powder
Dosage: 0.1 mL (~0.01-0.02 g)
Species: Rabbits; Albino, New Zealand
Age: Adult
Weight: Not reported
Source: Davidson's Mill Farm, South Brunswick, NJ

Conclusion:

1. **Toxicity Category:** III (Minimal irritant)
2. **Classification**: Acceptable

Procedure (including deviations from 870.2400): None

Observations	Number "positive"/number tested			
	Hours			
	1	24	48	72
	Unwashed eyes			
Corneal Opacity	0/6	0/6	0/6	0/6
Iritis	0/6	0/6	0/6	0/6
Conjunctivae:				
Redness[a]	1/6	0/6	0/6	0/6
Chemosis[a]	3/6	1/6	0/6	0/6
Discharge[a]	0/6	0/6	0/6	0/6

[a]Score of 2 or more considered to be "positive."

Summary: No corneal opacity or iritis was noted during the study. Within one hour after test material instillation, one rabbit exhibited conjunctival redness (score of 2) and three rabbits had conjunctival chemosis (score of 2) with resolution by 24 hours. One rabbit had conjunctival chemosis (score of 2) at 24 hours with resolution by 48 hours. All scores were zero by 72 hours. The highest average ocular irritation index was 5.7 recorded one hour after initiation. This classifies the test material as a mild irritant.

DATA REVIEW FOR PRIMARY DERMAL IRRITATION TESTING (870.2500, formerly §81-5))

Product Manager: 03
MRID No.: 44613708

Contract Reviewer: Susan Chang
EPA Reviewer: Byron T. Backus, Ph.D.
Study Completion Date: June 24, 1998
Study No.: 5874

Testing Facility: Product Safety Labs
Author: Wnorowski, G.

Quality Assurance (40 CFR §160.12): Included (p. 16)

Test Material: DRI-OUT™ (>99.7% Amorphous silica gel); Lot 7011; fine white powder
Dosage: 0.5 g dry weight basis (The test material was moistened with distilled water to achieve a dry paste by preparing a 25% w/w mixture.)
Species: Rabbits; Albino, New Zealand
Age: Adult
Weight: Not reported
Source: Davidson's Mill Farm, South Brunswick, NJ

Conclusion:

1. **Toxicity Category:** IV (not an irritant)
2. **Classification**: Acceptable

Procedure (including deviations from 870.2500): "Preliminary solubility testing conducted by PSL, indicated that mixtures in excess of 25% (i.e., 30-80%) were too dry to be classified as a paste."

Results: PDIS = 0.0 (Not an irritant). No irritation was noted on any rabbits during the study.

Special Comments: None

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DATA REVIEW FOR DERMAL SENSITIZATION TESTING (870.2600, formerly §81-6))

Product Manager: 03
MRID No.:44613709

Contract Reviewer: Susan Chang
EPA Reviewer: Byron T. Backus, Ph.D.
Study Completion Date: June 24, 1998
Study No.: 5875

Testing Facility: Product Safety Labs
Author: Wnorowski, G.

Quality Assurance (40 CFR §160.12): Included (p. 23)

Test Material: DRI-OUT™ (>99.7% Amorphous silica gel); Lot 7011; fine white powder
Positive Control Material: 1-Chloro-2,4-dinitrobenzene (DNCB)
Species: Guinea pigs; Albino, Hartley
Age: Young adult
Weight: Males: 340-415 g
Source: Davidson's Mill Farm, South Brunswick, NJ
Method: Buehler

Conclusion:

1. **There is no indication that this product is a dermal sensitizer.**
2. **Classification**: Acceptable

Procedure (including deviations from 870.2600): For the induction phase, 0.15 g of the 95% w/w test material in distilled water was applied under occlusion for six hours once each week for three weeks. Guinea pigs were left untreated for thirteen days before challenge. The animals were challenged with 0.15 g of the 95% w/w test material in distilled water under occlusion at naive sites for 6 hours. A naive control group was treated with 0.15 g of the 95% w/w test material in distilled water at challenge only. The positive control group animals were induced with 0.4 mL of 0.08% DNCB in 80% aqueous ethanol and challenged with 0.04% w/w DNCB in acetone. A naive positive control group was challenged with 0.04% w/w DNCB in acetone at challenge. Reactions were scored 24 and 48 hours post exposure.

Results: One test animal was euthanized due to an injury prior to the third induction. No reactions were noted on any test or naive control animals after induction or challenge. The DNCB positive control and naive control animals responded appropriately.

Special Comment: The test material, as used in this assay, was applied as 95% w/w in distilled water. However, in the dermal irritation study (MRID 44613708) it is stated (p. 8) that "the sample was applied as a dry paste by preparing a 25% w/w mixture in distilled water. Preliminary solubility testing conducted by PSL indicated that mixtures in excess of 25% (i.e. 30-80%) were too dry to be classified as a paste."

ACUTE TOX ONE-LINERS

1. **DP BARCODE:** D248699
2. **PC CODE:** 072602
3. **CURRENT DATE:** October 9, 1998
4. **TEST MATERIAL:** DRI-OUT™ (>99.7% Amorphous silica gel); Lot 7011; fine white powder

Study/Species/Lab Study #/Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity rat/Product Safety Labs, 5870/6-24-98	44613704	LD_{50} > 5000 mg/kg (males, females, combined)	IV	A
Acute dermal toxicity [a,b] rat/Product Safety Labs, 5871/6-24-98	44613705	LD_{50} > 5000 mg/kg (males, females, combined)	IV	A
Acute inhalation toxicity rat/Product Safety Labs, 5872/6-24-98	44613706	LC_{50} > 2.22 mg/L (males, females, combined)	IV	A
Primary eye irritation rabbit/Product Safety Labs, 5873/6-24-98	44613707	Minimal irritant; no corneal opacity or iritis noted; conjunctival redness on 1/6 rabbits and conjunctival chemosis on 3/6 rabbits at 1 hour with resolution by 24 hours; conjunctival chemosis in 1/6 rabbits at 24 hours with resolution by 48 hours. All scores were zero by 72 hours.	III	A
Primary dermal irritation [a] rabbit/Product Safety Labs, 5874/6-24-98	44613708	Not an irritant	IV	A
Dermal sensitization guinea pig/Product Safety Labs, 5875/6-24-98	44613709	Not a sensitizer	--	A

Core Grade Key: **A =Acceptable, S = Supplementary, U = Unacceptable, V = Self Validated**

[a]The test material was moistened with distilled water to achieve a dry paste by preparing a 25% w/w mixture.
[b] Dosage based on dry weight basis